

Application No. 10/634,331
Applicant: Alan J. POLITO et al.

REMARKS

Amendment of the Claims and Claim Status

Claims 98-116 are pending in this application. Of these, Claims 107-116 are withdrawn from consideration, Claim 100 is canceled, and Claims 98-106 are currently under consideration.

Claim 98 has been amended to recite “an apparatus useful for detecting the addition of a sample to a test strip in a lateral flow assay” and to remove the recitation that “the analyte is detected by analysis of reflectance data from one or more sectors of the test strip performed by the apparatus.”

Claim 99 has been amended to recite that the heating element is “positioned to lie under and contact the test strip when the test strip is in place.”

No new matter has been introduced by the foregoing amendments.

Claim Objections

The objection to Claim 100 is moot in light of Applicants’ cancellation of the claim.

Rejection under 35 U.S.C. §112, 2nd paragraph

Claims 98-106 have been rejected under 35 USC 112, second paragraph, as being incomplete for failing to provide a cooperative structural relationship that accounts for the apparatus’ abilities. Although the recitation of the apparatus’ functionality is in the preamble of the claim, which is not part of the claim limitation, in the interest of expediting prosecution, Applicants have amended claim 98 to clarify that the apparatus is useful for “detecting the addition of a sample to a test strip in a lateral flow assay.” As such, withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §112, 1st paragraph

Claims 98-106 have been rejected under 35 USC 112, first paragraph, as including new matter. In particular, it seems that the rejection is directed to an amendment in Claim 98 that was made in the previous response. Applicants respectfully submit that this rejection is moot in light of Applicants’ current amendment to remove the amendment made in the previous response. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §102

Claims 98-106 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Zweig (USPN 5,554,531). Applicants respectfully submit that Zweig does not teach an “autostart means comprising a capacitance sensor” as provided in the pending claims. In Zweig, the sensing of sample addition to a test article is achieved instead by measuring the electrical resistance across a portion of the bibulous matrix to which the sample is applied. Electrical resistance of a material is the measure of a material’s resistance to current. See lines 14-39, column 4 of Zweig. The sensing feature in Zweig operates on the principle that the adding of liquid sample changes the resistivity of the material, *i.e.* the bibulous matrix, at the site of application, which in turn changes the resistance of the object made of that material, *i.e.* the test article. In this manner, the lowered electrical resistance across that portion of the test article to which sample has been applied serves as a trigger for initiating a timing cycle.

In contrast, our invention provides “an autostart means comprising a capacitance sensor” for sensing the addition of sample to a test strip. Generally, a capacitor consists of two conducting plates, which could be of any shape or size, separated by an insulating material called a dielectric or dielectric layer. As generally defined, capacitance is a measure of how much charge must be put on the conducting plates of a capacitor to produce a certain potential between them. Referring to lines 23-31, page 22 of the instant specification, the sensing feature in our invention operates on the basis that the test strip, which forms a portion of the dielectric layer, has a certain dielectric constant when it is dry, *i.e.* before the addition of sample. After the addition of sample, the dielectric constant of the application region is increased, thereby causing the capacitance between the sensors to change. The sensors essentially serve as the capacitor plates and the change in capacitance between the sensors in turn signals the addition of sample. Thus, the present invention is different from and is not anticipated by Zweig. Withdrawal of the rejection is respectfully requested.

Double Patenting

Claims 98-101 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, and 5-8 of U.S. Patent No.

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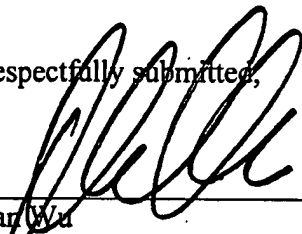
6,136,610. Applicants will file a terminal disclaimer in compliance with 37 CFR 1.321(c) once the claims of the present application are indicated as allowable but for the double patenting issue set forth herein.

In view of the foregoing amendments and remarks, it is believed that the application as a whole is in form for allowance. Should the Examiner have any continuing objections, the Applicant respectfully asks the Examiner to contact the undersigned at 415-442-1340 in order to expedite allowance of the case. Authorization is granted to charge any outstanding fees due at this time for the continued prosecution of this matter to Morgan, Lewis & Bockius LLP Deposit Account No. 50-0310 (matter no. 064881-5005-US03).

Respectfully submitted,

Date: January 9, 2006

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